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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,725	02/27/2004	Hea Young Park Choo	DE-1557	9620

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,725	PARK CHOO ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 7* is/are rejected.

7)☒ Claim(s) *4, 5 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed October 13, 2006 is acknowledged. Claim 10 was presented as a new claim in the Reply filed April 26, 2006. Claims 8 and 9 are presently canceled. Claims 1-7 and 10 remain under consideration.

A Declaration under 37 CFR 1.132 by Hea Young Park Choo filed October 13, 2006 is further acknowledged.

Claims 1-7 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action, as failing to comply with the written description requirement. It was asserted the claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Claim 10 was inadvertently omitted from the rejection.

Upon reconsideration, Table 4 on page 18 demonstrates inhibition of 5-lipoxygenase activity for various compounds of the present invention. Accordingly the rejection of record of claims 1, 4-7 and 10 under 35 U.S.C. 112, first paragraph, is withdrawn. Applicants argue working examples are not required and present a Declaration under 37 CFR 1.132. Further, Applicants informally introduce eleven references, as Exhibits 1-11, to show a correlation between 5-lipoxygenase and various inflammatory conditions.

While it acknowledged that no working examples are required, based on the subjective determination that "good" 5-lipoxygenase inhibition activity is exhibited, Applicants have merely extrapolated to clinical efficacy prevention and treatment of such diverse pathologies as asthma, pertussis, psoriasis, arthritis, inflammatory bowel

disease, cystic fibrosis, bronchitis, gout, sepsis, cardiac myoischemia, cardiac anaphylaxis, ischemia and allergic rhinitis. The demonstration of a therapeutic effect following the administration of the compound of Example 9 would provide substantial support.

The referenced Declaration is drawn to a comparison of an alleged compound of formula I in comparison to zileuton, a known 5-lipoxygenase inhibitor. Efficacy of the one "inventive compound" in Table V, as a 5-lipoxygenase inhibitor in suppressing leukocyte infiltration in lung cells, is demonstrated in a mice model of asthma. However, the "inventive compound" is not one encompassed by instant claim one. As such, the showing is not commensurate in scope with the claims.

Accordingly, the rejection of claims 2 and 3 under 35 U.S.C. 112, first paragraph, is maintained. Applicants have not described with sufficient clarity those compounds of formula I that are contemplated for prevention or treatment of any of the recited leukotriene-related diseases.

In view of the various functionalities encompassed in the options for the compounds of instant formula I, steric hindrance and receptor selectivity, and in particular, the diverse etiologies and involved organ systems of the recited disease states of instant claim 2, the skilled artisan would reasonably require a more detailed description of treatment. Sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art is absent.

Claim Rejections - 35 USC § 112 (First Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the inhibition of 5-lipoxygenase activity, does not reasonably provide enablement for treatment and prevention regimens as recited in claims 2 and 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification provides no support for preventing or treating comprising administering a compound of instant formula I. This is a Scope of Enablement rejection.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled

artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention or treatment of asthma, pertussis, psoriasis, arthritis, inflammatory bowel disease, cystic fibrosis, bronchitis, gout, sepsis, cardiac myoischemia, cardiac anaphylaxis, ischemia and allergic rhinitis based on the subjective determination that "good" 5-lipoxygenase inhibition activity is exhibited. Given its broadest interpretation, an inhibitor of 5-lipoxygenase is a compound that antagonizes the enzymatic conversion of unsaturated fatty acids with oxygen to yield peroxides. Such enzyme inhibition affects diverse organ systems in an unpredictable manner.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the various areas of the medicinal arts.

Each particular type of pathology characterized by 5-lipoxygenase activity has its own specific characteristics and etiology. The broad recitation "preventing or treating a leukotriene-related disease" in claim 2 is inclusive of many conditions that presently have no established successful therapies. A successful treatment modality for one of the recited disease states does not presage success for preventing that same disease. Accordingly, the claims lack a credible asserted or well established utility.

The breadth of the claims

The claims are very broad and inclusive of disorders of diverse etiology.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples in which any of the disclosed compounds is administered to treat or prevent any of the recited disease states. No guidance is provided to prevent any type of leukotriene-related disease. Such an assertion is clearly beyond the scope of the instantly claimed invention. The term "prevent" is an absolute definition that means to stop from occurring and thus requires a higher standard for enablement than does "therapeutic" or "treat". It is well established in the medical arts that the vast majority of diseases suffered by mankind cannot be totally prevented with current therapies.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound would be preferred for preventing or treating any of the recited diseases that are encompassed in the claim language. No direction is provided to distinguish therapy among the various types of leukotriene-related diseases or among the compounds that are disclosed in the specification. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic agent to treat any particular type of leukotriene-related disease, one skilled in the medicinal arts would have to test extensively many disclosed compounds to discover which particular type of recited leukotriene-related disease responds to a particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested,

undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Considering the state of the art as disclosed by the prior art of record, the high unpredictability of preventing leukotriene-related disease and the lack of guidance provided by the specification, one of ordinary skill in the art would be burdened with undue experimentation to prevent or treat leukotriene-related diseases comprising administering the instantly claimed antagonists of 5-lipoxygenase. Prevention entails the complete and absolute inhibition of the onset of a disease and any manifestation of the disease entirely.

Applicants have provided experimental data for 25 compounds that inhibit 5-lipoxygenase activity. Given the modest positive results, one skilled in the art would not accept the assertion that these compounds (or even a representative number or compounds) of Formula I could be used as prevention of asthma, pertussis, psoriasis, arthritis, inflammatory bowel disease, cystic fibrosis, bronchitis, gout, sepsis, cardiac myoischemia, cardiac anaphylaxis, ischemia and allergic rhinitis. It would take undue experimentation, with no assurance of success, to practice the invention commensurate in scope with the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Elnima et al., Antimicrobial Agents and Chemotherapy.

Elnima teaches the administration of various benzoxazole derivatives that exhibit antibacterial and antifungal activities. Such activities are septic activities, i.e., they relate to the presence of pathogenic organisms or their toxins in the blood or tissues. See page 30, compounds III, V and VI, wherein the depicted R groups are among those encompassed by the instant R^2 group of instant formula I. Basic truths of nature cannot be owned. Accordingly, these known benzoxazole derivatives inherently inhibit 5-lipoxygenase activity.

The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 1254, 195 USPQ 430, 433 (CCPA 1977).

Chang et al., Chemistry Letters, is cited to show further the state of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-

0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

December 19, 2006

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER